

Food and Drug Administration, HHS

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and inflammation associated with these conditions.

(2) The drug is administered intramuscularly at the following recommended daily dosage:

Weight of animal in pounds	Dosage in milligrams
Up to 10	1.0
10 to 25	2.0
25 and over	4.0

Dosage should be adjusted according to the weight of the animal, the severity of the symptoms, and the response noted. Dosage by injection should not exceed 3 days of therapy. With chronic conditions intramuscular therapy may be followed by oral administration of flumethasone tablets at a daily dose of from 0.0625 to 0.25 milligram per animal.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975. Redesignated at 44 FR 16011, Mar. 16, 1979, as amended at 61 FR 5507, Feb. 13, 1996]

§ 522.960c Flumethasone solution.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 0.5 milligram flumethasone.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is used as follows:

(1) *Horses*—(i) *Amount.* 1.25 to 2.5 milligrams daily, intravenously, intramuscularly, or intra-articularly.

(ii) *Indications for use.* It is used for the treatment of musculoskeletal conditions due to inflammation, where permanent structural changes do not exist, e.g., bursitis, carpalis, osselets, and myositis; and allergic states, e.g., hives, urticaria, and insect bites.

(iii) *Limitations*—(a) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(b) When a long-term therapy is used, the dose should be individually adjusted to the minimum maintenance dose. A protein-rich diet is useful in

dogs and cats on long-term therapy to counteract nitrogen loss if it should occur. A small amount of potassium chloride daily in the diet will counteract excessive potassium loss if this is present.

(c) It has been demonstrated that corticosteroids, especially at high dose levels, may result in delayed wound and fracture healing.

(d) Flumethasone may be administered to animals with bacterial diseases provided appropriate antibacterial therapy is administered simultaneously.

(e) The drug is not to be used in horses intended for slaughter for food purposes.

(f) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs*—(i) *Amount.* 0.0625 to 0.25 milligram daily, intravenously, intramuscularly, or subcutaneously; 0.125 to 1.0 milligram daily, intralesionally, depending on the size and location of the lesion; 0.166 to 1.0 milligram daily, intra-articularly, depending on the severity of the condition and the size of the involved joint.

(ii) *Indications for use.* It is used for the treatment of musculoskeletal conditions due to inflammation of muscles or joints and accessory structures where permanent structural changes do not exist, e.g., arthritis, osteoarthritis, disc syndrome, and myositis (in septic arthritis, appropriate antibacterial therapy should be concurrently administered); certain acute and chronic dermatoses of varying etiology to help control associated pruritus, irritation, and inflammation; otitis externa in conjunction with topical medication; allergic states, e.g., hives, urticaria, and insect bites; and shock and shock-like states by intravenous administration.

(iii) *Limitations.* See paragraph (c)(1)(iii) of this section.

(3) *Cats*—(i) *Amount.* 0.03125 to 0.125 milligram daily intravenously, intramuscularly, or subcutaneously.

(ii) *Indications for use.* It is used for the treatment of certain acute and chronic dermatoses of varying etiology to help control associated pruritus, irritation, and inflammation.

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(iii) *Limitations.* See paragraph (c)(1)(iii) of this section.

[44 FR 16011, Mar. 16, 1978, as amended at 61 FR 5507, Feb. 13, 1996]

§ 522.970 Flunixin meglumine solution.

(a) *Specifications.* The drug contains 50 milligrams of flunixin per milliliter of aqueous solution.

(b) *Sponsors.* See 000061 in § 510.600(c) of this chapter for use as in paragraph (d) of this section. See 000856 and 059130 for use as in paragraph (d)(1) of this section only.

(c) *Related tolerances.* See § 556.286 of this chapter.

(d) *Conditions of use—(1) Horses—(i) Amount.* 0.5 milligram of flunixin per pound of body weight (1 milliliter per 100 pounds) per day.

(ii) *Indications for use.* For alleviation of inflammation and pain associated with musculoskeletal disorders, and alleviation of visceral pain associated with colic.

(iii) *Limitations.* For musculoskeletal disorders, administer intravenously or intramuscularly for up to 5 days. For colic, administer a single dose intravenously—treatment may be repeated when signs of colic recur. Caution: The effect of this drug on pregnancy has not been determined. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Beef cattle and nonlactating dairy cattle—(i) Amount.* 1.1 to 2.2 milligrams per kilogram of body weight (0.5 to 1 milligram per pound, 1 to 2 milliliters per 100 pounds), once a day as a single dose or divided into 2 doses administered at 12-hour intervals for up to 3 days.

(ii) *Indications for use.* For control of pyrexia associated with bovine respiratory disease and endotoxemia. Also indicated for control of inflammation in endotoxemia.

(iii) *Limitations.* Do not slaughter for food use within 4 days of last treatment. Not for use in lactating or dry dairy cows. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. Do not use in bulls intended for breeding as reproductive effects in this class of cattle have not been studied. Federal law re-

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stricts this drug to use by or on the order of a licensed veterinarian.

[42 FR 39103, Aug. 2, 1977, as amended at 52 FR 7832, Mar. 13, 1987; 60 FR 54942, Oct. 27, 1995; 62 FR 22888, Apr. 28, 1997; 63 FR 38749, July 20, 1998]

§ 522.995 Fluprostenol sodium injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains fluprostenol sodium equivalent to 50 micrograms of fluprostenol.

(b) *Sponsor.* See 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* 0.55 microgram fluprostenol per kilogram of body weight.

(2) *Indications for use.* The drug is used in mares for its luteolytic effect to control the timing of estrus in estrous cycling and in clinically anestrus mares that have a corpus luteum.

(3) *Limitations.* Administer by intramuscular injection only. *Warning:* Not for use in horses intended for food. For veterinary use only. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. In the early stages, women may be unaware of their pregnancies. Fluprostenol is readily absorbed through the skin and can cause abortion and/or bronchospasms. Direct contact with the skin should therefore be avoided. Accidental spillage on the skin should be washed off immediately with soap and water.

[44 FR 52191, Sept. 7, 1979, as amended at 47 FR 22092, May 21, 1982]

§ 522.1002 Follicle stimulating hormone.

(a)(1) *Specifications.* Each package contains 2 vials. One vial contains dry, powdered, porcine pituitary gland equivalent to 75 units (NIH-FSH-S1) of follicle stimulating hormone. The other vial contains 10 milliliters of aqueous diluent.

(2) *Sponsor.* See 059521 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) *Dosage.* 12.5 units of follicle stimulating hormone